UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,833	04/21/2000	Patrick Mark Curry	273012011100	6384

25225 7590 04/09/2004

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/556,833	CURRY ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on December 8, 2003 has been entered. Claims 1-3 have been amended.

2. Claims 1-16 are pending in the application and are currently under continued prosecution.

Grounds of Objection and Rejection Withdrawn

3. Unless specifically reiterated in this Office Action, the grounds of objection and rejection set forth in the previous Office Action mailed June 6, 2003 have been withdrawn.

Response to the Amendment

4. Applicant's grounds of traversal of the rejection of claims 1-16 under 35 USC § 103(a) for the reason set forth in section 9 of the Office action mailed June 6, 2003 have been considered, but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 2, 3, 5, 7, 9-11, 13, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998), as evidenced by Kresl et al. (*Tumour Biol.* **20**: 72-87, 1999).

Korbelik et al. teaches a method for treating tumors in a subject comprising administering to the subject effective amounts of a green porphyrin, namely

benoporphyrin derivative monoacid (BPD-MA), Photofrin™, or mTHPC chlorin, and an immunoadjuvant, namely a mycobacterial cell wall extract or live Bacillus Calmette-Guerin (BCG) vaccine and irradiating the subject with light comprising a wavelength absorbed by said photosensitizer; see, e.g., "Abstract" at page 151; "Materials and Methods" at page 152; and "Results" at page 154. Korbelik et al. teaches administering the immunoadjuvant as an adjuvant to photodynamic therapy (PDT) enhances the antitumor effects of PDT; see, e.g., "Abstract" and "Discussion". Korbelik et al. teaches a curative effect of the treatment, since the treated mice remain tumor-free; see, e.g., "Fig. 1" at page 153. Korbelik et al. teach an effective amount of the photosensitizer is in the range of 0.05 to 10 milligrams of photosensitizer per kilogram of subject; see "Fig. 2" at page 154. Korbelik et al. teaches irradiation is localized to the tumor; see "Materials and Methods" at page 152, column 1. Korbelik et al. teaches the photosensitizer is administered intravenously (*or systemically*); see "Fig. 2" at page 154. Korbelik et al. teaches the photosensitizer can be administered to the subject, and the subject can be irradiated - before the immunoadjuvant is administered to the subject; see "Results" at page 154.

Korbelik et al. teaches the preparation of mycobacterial cell wall extract, which is used is purified and deproteinized, and sold under the tradename Regressin by Bioniche Inc. (London); see "Materials and Methods" at page 152, column 1. Therefore, absent a showing any difference, the bacterial cell wall extract of Korbelik et al. is deemed the same as or otherwise deemed to comprise, the immunoadjuvant of the claims, which is "mycobacterial cell wall skeletons".

As evidenced by Kresl et al., mice implanted subcutaneously with mouse mammary adenocarcinoma line EMT6 cells are at risk for developing tumors from metastasis of the primary tumor. Since Korbelik et al. teaches a curative effect by the treatment, since the treated mice remain tumor-free, it appears the method of Korbelik et al. can be used to prevent or inhibit in a subject at risk for developing tumors from metastasis of a primary tumor the development of such tumors.

For clarity of record, it is noted a rejection of claims under 35 USC § 102(b), as being anticipated by Korbelik et al., was previously set forth in section 7 of the Office

action mailed April 10, 2001. The rejection set forth in that Office action is improper because Korbelik et al. is not prior art under § 102(b). Kobelik et al., however, is prior art under § 102(a), and upon reconsideration of the teachings of the reference, it has been determined the reference anticipates the subject matter of claims 2, 3, 5, 7, 9-11, 13, and 14. It is further noted, in response to the Office action mailed April 10, 2001, Applicant traversed the rejection, arguing the following:

> Instant claim 3 is directed to methods comprising administration to "a subject clinically diagnosed with a primary tumor" while Korbelik et al. is directed to the treatment of transplanted tumors in mice. The scope of claim 3 thus does not include the mice treatments of Korbelik et al. and the rejection fails to provide a single reference which meets all the limitations of the instant claims. A *prima facie* case of anticipation thus has not been presented, and the rejection ' may be properly withdrawn (amendment filed August 10, 2001 at page 8, paragraph 4).

As Applicant's argument may be considered relevant to a traversal of the instant rejection, that argument has been carefully considered but not found persuasive. The specification does not define the term "subject"; the term is therefore given its ordinary meaning. Given it ordinary meaning, the "subject" can be a mouse; and certainly the mice used by Korbelik et al. are the subjects of their study. Furthermore, the specification does not define the term "clinically diagnosed". The On-line Medical Dictionary (published at the Dept. of Medical Oncology, University of Newcastle upon Tyne © Copyright 1997-2004 - The CancerWEB Project), which is available on the Internet at http://cancerweb.ncl.ac.uk/omd/, defines the term "clinical diagnosis" as: "A diagnosis made from a study of the signs and symptoms of a disease". At page 152, column 1, Korbelik et al. teaches the tumors were treated when they reached 5-7 mm in diameter. Korbelik et al. thus discloses a study of the signs of a tumor in their subjects, which rendered a clinically diagnosis.

Finally, it is noted for clarity of record that the previous Office action mistakenly indicates Korbelik et al. does not teach BPD-MA. The term "BPD-MA", as recited in claim 14, had been incorrectly interpreted as designating "BPD monoacid ring A", rather than as designating a "benzoporphyrin derivative monoacid", the latter of which, at page 10, line 18, the specification distinguishes from former, using the designation "BPD-MA-

A" to indicate the former. At page 152, column 1, Korbelik et al. teaches a green porphyrin, which is a "benzoporphyrin derivative monoacid", *or BPD-MA*.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of US Patent No. 5,095,030 A.

Korbelik et al. teaches that which is set forth in the above rejection of claims 2, 3, 5, 7, 9-11, 13, and 14 under 35 USC § 102(a).

However, Korbelik et al. does not expressly disclose the method can be used to treat in a subject, tumors that result from the metastasis of a primary tumor (claim 1); nor does Korbelik et al. teach the effective amount of the photosensitizer can be in the range of 0.05 to 1.0 milligrams of photosensitizer per kilogram of subject (claim 6).

US Patent No. 5,095,030 A ('030) teaches the photosensitizer BPD-MA can be used at dosages in the range of 0.05 to 1.0 milligrams per kilogram of subject to effectively destroy a tumor by photodynamic therapy (PDT) photosensitizer; see, e.g., column 16, line 21, and column 22, Tables 6 and 7. '030 teaches photodynamic therapy alone can prevent the development of tumors in mice; see column 22, Table 6.

Since '030 discloses mice treated with photodynamic therapy alone remain tumor-free following treatment, while Korbelik et al. teaches administering the immunoadjuvant as an adjuvant to photodynamic therapy (PDT) enhances the antitumor effects of PDT, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to use an amount of BPD-MA in the range of 0.05 to 1.0 milligrams per kilogram of subject in practicing the method of Korbelik et al.,

because '030 teaches amounts in that range are effective to treat in a subject, a tumor resulting from metastasis of a primary tumor. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat cancer in patients diagnosed with a primary tumor, or at risk for developing metastases of a metastatic primary tumor.

9. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of Momma et al. (*Cancer Research* **58**: 5425-5431, 1998).

Korbelik et al. teaches that which is set forth in the above rejection of claims 2, 3, 5, 7, 9-11, 13, and 14 under 35 USC § 102(a).

However, Korbelik et al. does not expressly disclose the method can be used to treat in a subject, tumors that result from the metastasis of a primary tumor (claim 1); nor does Korbelik et al. disclose the subject can have previously undergone anticancer therapy (claim 4).

Momma et al. teaches a BPD-MA can be used to effectively treat, inhibit, or prevent primary and secondary tumors by photodynamic therapy; see, e.g., "Abstract". Momma et al. teaches the treatment can be used as an adjuvant to surgical treatment, so Momma et al. teaches the subject has previously undergone anticancer therapy.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to use the method of Korbelik et al. to treat in a subject, a tumor resulting from metastasis of a primary tumor, because Momma et al. teaches photodynamic therapy can be used to effectively treat, inhibit, or prevent primary and secondary tumors, while Korbelik et al. teaches administering the immunoadjuvant as an adjuvant to photodynamic therapy (PDT) enhances the antitumor effects of PDT. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat in a subject, a tumor arising from metastasis of a primary tumor.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of US Patent No. 6,290,712 B1, or alternatively over Korbelik et al. in view of US Patent No. 5,095,030 A

or Korbelik et al. in view of Momma et al. (*Cancer Research* **58**: 5425-5431, 1998), as applied to the rejections of claim 1 above, and in further view of US Patent No. 6,290,712 B1.

Korbelik et al. and Momma et al. teach that which is set forth above.

However, while Korbelik et al. teaches the immunoadjuvant is administered subcutaneously under the tumor (see "Materials and Methods", page 152), Korbelik et al. does not expressly teach or suggest that the immunoadjuvant can be administered intratumorally (claim 8).

US Patent No. 6,290,712 B1 ('712) that the immunoadjuvant can be administered intratumorally (see, e.g., column 15, lines 10-20) in practicing a method for treating a neoplasm in a subject comprising administering to the subject a chromophore and an immunoadjuvant, and irradiating the tumor at a wavelength absorbed by the chromophore to induce the destruction of the tumor and to stimulate the immune system so that further neoplastic cellular proliferation in the subject is prevented or inhibited (see, e.g., abstract). '712 teaches that upon absorption of a particular wavelength of light, suitable chromophores, *or photosensitizers* should have the ability "to create thermal energy, to evolve singlet oxygen and other active molecules, or to be toxic in their own right" (column 7, lines 40-43). '712 teaches a suitable immunoadjuvant should non-specifically stimulate the immune system; and '712 discloses examples of such suitable immunoadjuvants, including a component of bacterial cell walls (column 9, lines 10-15). '712 teaches several advantages of the disclosed invention over conventional and unconventional treatment modalities, but emphasizes the "combination of sensitizer and immune-stimulation adjuvant is the key" (column 5, lines 63-65). '712 discloses, the "most significant advantage [of their disclosed invention] is a combined acute and chronic tumor destruction" (column 5, lines 65 and 66). '712 demonstrates the utility of an exemplary invention to treat both primary and metastatic tumors, the latter of which arose as metastases of a primary tumor, in Figures 1 and 2, and Figures 3 and 4, respectively. In Figure 5, '712 demonstrates the use of an exemplary invention to prevent of the development of metastases of a primary tumor in a subject.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer the immunoadjuvant intratumorally in practicing the method of Korbelik et al., because '712 teaches the immunoadjuvant can be administered intratumorally in practicing a method for treating, inhibiting, or preventing a tumor in a subject comprising administering to the subject a photosensitizer and an immunoadjuvant and irradiating the tumor. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat cancer in a subject.

11. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of US Patent No. 5,579,554 A, or alternatively over Korbelik et al. in view of US Patent No. 5,095,030 A or Korbelik et al. in view of Momma et al. (*Cancer Research* **58**: 5425-5431, 1998), as applied to the rejections of claim 1 above, and in further view of US Patent No. 5,579,554 A.

Korbelik et al. and Momma et al. teach that which is set forth above.

However, while Korbelik et al. teaches the immunoadjuvant is administered subcutaneously under the tumor (see "Materials and Methods", page 152), Korbelik et al. does not expressly teach or suggest that the immunoadjuvant can be administered intratumorally (claim 8) or systemically (claim 12).

US Patent No. 5,579,554 A ('554) teaches an aqueous mycobacterial cell wall extract, which can be injected directly into the tumor or it can be given systemically (column 5, lines 14-24). '554 teaches administering to a subject the disclosed aqueous mycobacterial cell wall extract is an effective means for treating cancer; see, e.g., abstract. '554 discloses: "The cancers can be primary or metastatic" (column 3, lines 42-45). The advantage that the immunoadjuvant of '554 provides is that it does not need to be suspended in oil and therefore its use precludes the development of granulomas in subjects treated with immunoadjuvants comprising oil (column 4, lines 5-9; column 2, lines 39-42).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer the immunoadjuvant intratumorally or systemically in

practicing the method of Korbelik et al. using the aqueous mycobacterial cell wall extract of '554, because '554 teaches the immunoadjuvant can be administered intratumorally or systemically. Because '554 teaches administering to a subject the disclosed aqueous mycobacterial cell wall extract is an effective anticancer treatment, while Korbelik et al. teaches administering an immunoadjuvant, such as the immunoadjuvant of '554 as an adjuvant to photodynamic therapy (PDT) enhances the antitumor effects of PDT, the artisan would have had a reasonable expectation of success in doing so at the time of the invention. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat cancer in a subject.

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of US Patent No. 6,071,944 A, or alternatively over Korbelik et al. in view of US Patent No. 5,095,030 A or Korbelik et al. in view of Momma et al. (*Cancer Research* **58**: 5425-5431, 1998), as applied to the rejections of claim 1 above, and in further view of US Patent No. 6,071,944 A.

Korbelik et al. and Momma et al. teach that which is set forth above.

However, none of the references expressly teach or suggest that an additional step comprising additional irradiation, before irradiation with light of a wavelength absorbed by the photosensitizer, with a light of a wavelength that increases penetration of the wavelength of light absorbed by the photosensitizer (claim 15).

US Patent No. 6,071,944 A teaches a method for treatment of malignant melanoma, which also comprises administering to the subject a photosensitizer and then irradiating the subject at a wavelength at which the photosensitizer absorbs light; see, e.g., abstract. '944 discloses that the efficacy of photodynamic therapy can be hampered if lesions are pigmented, which is often the case with highly metastatic melanoma, because the pigmented tumor cells are less responsive; the lack of response attributed to optic filtering by melanin granules within the cell; see, e.g., column 1, lines 29-38. As a solution to the problem, '944 teaches that pretreatment of pigmented tumors with high peak power light (such as 1064 nm light) enhances their

susceptibility to conventional photodynamic therapy; see, e.g., column 3, lines 35-46. Therefore, '944 teaches that photodynamic therapy is more efficacious when the subject is irradiated at a wavelength that improves penetration of the wavelength of light at which the photosensitizer absorbs.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add a step in practicing the method of Korbelik et al. comprising an additional irradiation with light of a wavelength that improves penetration of the absorbed light before irradiating the subject at the wavelength absorbed by the photosensitizer, because '944 teaches that photodynamic therapy is more efficacious when the subject is first irradiated at a wavelength that improves penetration of the wavelength of light at which the photosensitizer absorbs, especially if the tumor cells are pigmented. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat cancer in a subject.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korbelik et al. (*J. Photochem. Photobiol. B: Biology* **44**: 151-158, 1998) in view of Johnston et al. (*J. Natl. Cancer Inst.* **83**: 1240-1245, 1991) and US Patent No. 4,912,094 A, or alternatively over Korbelik et al. in view of US Patent No. 5,095,030 A or Korbelik et al. in view of Momma et al. (*Cancer Research* **58**: 5425-5431, 1998), as applied to the rejections of claim 1 above, and in further view of Johnston et al. (*J. Natl. Cancer Inst.* **83**: 1240-1245, 1991) and US Patent No. 4,912,094 A.

Korbelik et al. and Momma et al. teach that which is set forth above.

However, while Korbelik et al. teaches or suggests the immunoadjuvant is a mycobacterial cell wall extract comprising mycobacterial cell wall skeletons, the reference does not expressly teach or suggest an immunoadjuvant comprising mycobacterial cell wall skeleton *and de-3-acylated lipid A* (claim 16).

Johnston et al. teaches an immunoadjuvant comprising purified mycobacterial cell wall skeleton and monophosphoryl lipid A (MPL). Johnston et al. teaches the immunoadjuvant can be administered more safely than Freund's complete adjuvant, since the immunoadjuvant induced fewer cutaneous toxic effects, but produced stronger

antibody and delayed-type hypersensitivity responses than Freund's complete adjuvant; see, e.g., the abstract. Johnston et al. discloses the combination of mycobacterial cell wall skeleton and monophosphoryl lipid A (MPL), as in DETOX, has been reported to have a synergistic effect (page 1243, column 2).

US Patent No. 4,912,094-A ('094) teaches that modified lipopolysaccharides, particularly de-3-O-acylated monophosphoryl lipid A and de-3-O-acylated diphosphoryl lipid A retain a high level of immunostimulating capacity but have the advantage of being considerably less endotoxic than naturally occurring lipopolysaccharide (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the method of Korbelik et al. using an immunoadjuvant comprising mycobacterial cell wall skeleton and de-3-acylated lipid A because Johnston et al. teach the combination of mycobacterial cell wall skeleton and MPL produces a synergistic effect, and because '094 teaches de-3-acylated lipid A is considerably less endotoxic than naturally occurring lipopolysaccharide. One of ordinary skill in the art at the time of invention would have been motivated to do so to treat cancer in a subject.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

15. Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 and 28-33 of copending Application No. 09/756,687 for the reason set forth in section 11 of the Office action mailed June 6, 2003.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

At Applicant's request, this issue will be held in abeyance until such time that patentable subject matter is indicated.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
April 2, 2004

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600